REMARKS

This paper is responsive to the Office Action mailed June 27, 2006. Presently, all claims 1-28 stand rejected.

The present application is directed to a system for permitting substantially leak-free percutaneous entry into a body vessel of a patient, such as a blood vessel, for withdrawing a bodily fluid from the vessel. According to independent claim 1, the percutaneous insertion system comprises a needle assembly, a needle hub attachment assembly, and an assembly comprising a hemostatic segment. The distal end of the needle assembly comprises an elongated needle for percutaneous entry into the vessel for withdrawing the fluid, and the proximal end comprises a needle hub. The distal end of the needle hub attachment assembly is configured for leak-free engagement with the needle hub. The distal end of the assembly comprising a hemostatic segment is configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The hemostatic segment is positioned at the proximal end of the assembly. The respective components are aligned such that a passageway for insertion of a wire guide is defined therethrough.

The assembly that comprises a hemostatic segment may comprise, for example, a wire guide inserter 40 (Fig. 2) or a wire guide holder 60 (Fig. 7). Wire guide inserters and wire guide holders are well known in the art. One particularly preferred example of a proximally-positioned hemostatic segment that may be positioned in a passageway of inserter 40 or holder 60 comprises a tapered valve 44, as illustrated in Fig. 4. Positioning hemostatic segment, or valve, 44 at the proximal end of wire guide inserter 40 (Fig. 2) or wire guide holder 60 (Fig. 6) inhibits the backflow of the body fluid, such as blood, through the proximal end of the inserter or holder. As shown in the figures, segment 44 has a central lumen 50 extending longitudinally therethrough, and preferably, tapers in the distal direction as shown. The presence of the taper allows blood to collect circumferentially on the exterior of the tapered portion of segment 44 within lumen 46. Any pressure within the system circumferentially will cause the taper

to collapse within the lumen, thereby sealing around the wire guide, or sealing completely if no wire guide is present. See, Application, page 8, lines 13-31. Although the tapered hemostatic segment 44 is preferred, other configurations may be substituted for segment 44. Non-limiting examples of alternative hemostatic segments for the wire guide assembly are shown in Figs. 5a and 5b, respectively.

Section 102(b) rejections.

Claims 1, 2, 5-11 and 13-16, 17, 18 and 20-24 were rejected under 35 U.S.C. §102(b) as being anticipated by Padilla et al. (USP 5,984,895). Padilla is directed to a blood containment device for use with a vascular entry needle. The device is said to provide visual and tactile confirmation that a blood vessel has been properly entered. According to the Examiner, Padilla discloses a vascular access device comprising a needle 20 and a hub 22, a hub attachment assembly 30 and a hemostatic segment permitting passage of the guidewire, the hemostatic segment having a slit valve 63, and tapering to an end hole 40.

(1) Claims 1, 2, 5-11 and 13-16.

Applicants respectfully submit that the percutaneous insertion system of claim 1, as well as dependent claims 2, 5-11 and 13-16, is not anticipated by Padilla. For example, as recited in independent claim 1, the distal end of the needle hub attachment assembly is sized and configured for leak-free engagement with the needle hub. The distal end of the assembly comprising a hemostatic segment is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. This arrangement is illustrated, e.g., at Figs. 2 and 7. As a result, each of the three portions, or "assemblies", of the inventive insertion system is axially aligned to permit efficient insertion of the needle, collection of a portion of the blood in a chamber, and provision of an inserter or holder for a wire guide, which inserter or holder includes a proximal

hemostatic valve. This arrangement provides a very compact, yet efficient, system for bloodless percutaneous entry.

The Examiner has identified structure in the Padilla device that is said to meet the limitations of the claimed configuration. However, Applicants respectfully submit that the Padilla device is structurally quite different than the claimed insertion system. For example, as understood, the Examiner has apparently identified blood containment device 30 in Padilla as meeting the limitation of a hub attachment assembly, and outer shell 38 as meeting the limitation of the assembly comprising a hemostatic segment. However, as is apparent from the figures, and particularly Fig. 3, the distal end of the outer shell 38 is not configured for leak-free engagement with the proximal end of the blood containment device 30, as claimed herein. Rather, the blood containment device 30 is positioned interiorly of shell 38, and it is the distal end of outer shell 38 that is engaged with the needle hub 22 (Fig. 3).

In addition to the foregoing, each of the "assemblies" of the claimed percutaneous insertion system includes a passageway extending between the respective proximal and distal ends of the particular assembly. The respective passageways are aligned to form a path for insertion of the wire guide into the body vessel. The allegedly corresponding elements identified by the Examiner do not have passageways aligned in this manner. See, for example, Fig. 3 wherein the passageways of containment device 30 and outer shell 38 are not aligned in the manner of the claimed invention. Rather, any passageways through containment device 30 and outer shell 38 would have to extend side-by side (parallel), or perhaps as part of a common line.

Applicants further call the Examiner's attention to a particularly preferred embodiment as claimed in dependent claim 8. According to claim 8, the valve tapers to an endhole having a diameter substantially the same as the diameter of the wire guide inserter or holder. As indicated above, this tapered configuration allows blood to collect circumferentially along the exterior of the tapered portion. As a result, circumferential pressure exerted around the valve within the system

will cause the taper to collapse and form a seal. Padilla does not teach such a tapered proximal valve.

Similarly, claim 5, as well as dependent claims 9 and 10 further describe an arrangement wherein the distal end of the assembly comprising the hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This is shown, for example, as tapered end 42 in Figs. 2 and 12, and as tapered end 61 in Fig. 7. According to the claims, the tapered distal end is sized and configured for engagement for leak-free engagement with the proximal end of the needle hub assembly. No such tapered end is provided in Padilla. The Examiner has cited end hole 40 as meeting this limitation, however end hole 40 is merely a luer lock fitting (Col. 6, lines 22-23) that is provided on the needle hub of the Padilla device. Luer lock fitting 40 is not part of the distal end of an assembly (e.g., such as wire guide inserter 40 or wire guide holder 60) comprising a hemostatic segment that is engageable with a needle hub attachment assembly pursuant to the present claims, nor does it taper to an endhole having a diameter substantially the same as the diameter of the sire guide.

(2) Claims 17, 18, and 20-24.

Independent claim 17 is directed to a percutaneous insertion system comprising a needle assembly having a first hemostatic segment, and an assembly engaged with the needle assembly and having a second hemostatic segment. The needle assembly comprises an elongated needle at its distal end for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The distal end of the assembly having the second hemostatic segment is sized and configured for leak-free engagement with the proximal end of the needle assembly. The second hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly, and has an opening permitting passage of a wire guide therethrough.

Applicants respectfully submit that this claim, as amended, as well as claims 18 and 20-24 depending therefrom, are also not anticipated by the Padilla

reference. Claim 17 has been amended to more clearly reflect the presence of two hemostatic segments, one of which is in each of the respective assemblies. The hemostatic segments are identified in the amended claims as respective first and second segments. The second segment comprises a valve positioned at the proximal end of the assembly. For example, in the embodiment shown in Fig. 12, the first hemostatic segment is shown as reference numeral 52. The second hemostatic segment is shown as reference numeral 44. Padilla neither teaches nor suggests an arrangement having dual hemostatic segments aligned along an insertion system as claimed, and in particular, neither teaches nor suggests a hemostatic segment in a needle assembly. The percutaneous insertion system of claim 17 need not have a separate needle hub attachment assembly, or alternatively, such attachment can comprise part of either of the respective assemblies recited in the claim.

Claims 22-24 are even further distinguished from Padilla. For example, the percutaneous insertion system of claim 22 includes the limitation of a valve that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. No such tapered valve is provided in Padilla. Similarly, claims 23 and 24 (dependent on claim 23) include the limitation of a wire guide inserter having a reverse flared tip, and wherein the proximal end of said needle hub attachment assembly is shaped to conform to said reverse flare to comprise said leak-free engagement. No such inserter is taught in Padilla.

Sec. 103(a) rejections.

Claims 3, 4, 12 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Padilla in view of Lynch et al (USP 5,438,993). Lynch was cited for teaching a guidewire holder as claimed in dependent claims 3, 4, 12 and 19. However, Lynch does not teach or suggest the arrangement of the respective assemblies as discussed above with reference to the Sec. 102(b) rejection of claim 1, nor does it teach or suggest the use of dual hemostatic segments of claim 17.

Thus, dependent claims 3, 4, 12 and 19 are allowable for at least the same reasons that independent claims 1 and 17 are allowable.

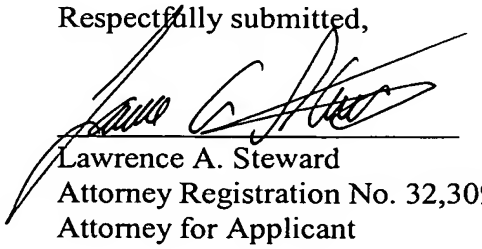
New claims.

Claims 25-28 have been cancelled, and new claims 29-32 have been added. Claim 29, dependent on claim 1, includes a second hemostatic segment that is positioned in the needle hub attachment assembly. One example of this arrangement is shown at Fig. 3 of the application. New independent claim 30 is directed to a percutaneous insertion system comprising a needle assembly and an assembly having a hemostatic segment. This claim differs from independent claims 1 and 17 in large part in that it more particularly describes the hemostatic segment as a valve that tapers in the distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide. This arrangement is also neither taught nor suggested in Padilla or the other references of record. Claims 31 and 32 are dependent on claim 30.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of the claims have been overcome, and that all claims 1-24 and 29-32 are in condition for allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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